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Rec'd 7-7-99

April 22, 1999

Dr. Jane E. Henney
Commissioner for Food and Drugs
Food and Drug Administration
5600 Fishers Lane, Room 14-71
Rockville, MD 20857

Dear Dr. Henney:

We, as representatives of the Congressional Caucus on Women's Issues, are writing to express our concerns about the proposed FDA rule regarding Medical Devices; Labeling for Menstrual Tampons; Ranges of Absorbency. If implemented, this rule will create an "ultra" category that would increase permissible tampon absorbency to 15-18 grams.

While we understand that some women have a need for a higher absorbency tampon we are concerned that allowing for a more absorbent tampon may lead to increased heath risks among women including an increased risk of Toxic Shock Syndrome (TSS). An additional concern is that there is a lack of accurate statistics on TSS cases and related deaths. Currently, reporting of TSS by the Centers for Disease Control and Prevention (CDC) is optional and uneven. Without accurate base-line data and lacking uniform, national data collection standards on TSS, it will be difficult to measure the impact of the "ultra" tampon.

We also feel there is a need for increased education targeted towards women, clarifying that an "ultra" tampon is not necessarily a "better" tampon. There appears to be a misconception among women that the classifications (e.g. "super", "super plus") of tampons refer to the amount of time a tampon can be used or its effectiveness. Women need to be better informed on how to choose the appropriate absorbency level.

Given the low awareness level among women of their TSS risk, uneven data collection of TSS cases, and the general misconception among women that increased absorbency tampons are "better", we fear that this new classification would lead women to think that they could use an "ultra" tampon for longer periods of time and that this could lead to an undetected rise in TSS.

Please advise us prior to releasing the final rule of the following:

1) How will potential increases in TSS cases will be monitored?

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2) What steps can be taken to increase women's awareness of how to choose the appropriate absorbency level and the dangers of selecting tampons that are too absorbent?

3) What was the rationale for not creating a name for the 15-18 gram classification of tampons when the other classifications were named?

We look forward to your prompt response.

Sincerely,

Carolyn B. Maloney

Lois Capps

Louise Slaughter

Nancy Pelosi

Sheila Jackson Lee

Karen Thurman

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KCK
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DIVISION OF REPRODUCTIVE
Abdominal, Ear, Nose And Throat, And Radiological Devices

CDRH EXECUTIVE CORRESPONDENCE TRACKING

MAY 3 1999

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Keywords: MENSTRUAL, TAMPON, LABELING, PROPOSED, FDA, RULE

Remarks:

Please send all comments regarding correspondence to Sharon Burgess's (SMD) electronic mail account.

Rec'd 7/7/99

To: Myrna Hanna

From: Colin Pollard
Chief, OB/GYN Devices Branch (HFZ-470)

Date: July 7, 1999

Subject: Maloney letter on Tampon Proposed Rule

Facsimile

Attached, as discussed, is the 4/22/99 Maloney letter to Henney, expressing reservations about the proposed rule to amend the tampon labeling reg.

Attachment

From the desk of...

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Answer: *The regulations do not specify a frequency or designate a specific individual to perform testing for this requirement* **or even that this equipment standard be tested at all**; *however, the facility is responsible for making sure the mammography equipment meets MQSA requirements. FDA has* **left the decision to test for compliance with this standard** ~~*both the test procedures and frequency*~~ *to the discretion of the facility.* **FDA recommends that** ~~*Such*~~ *conformance* ~~*would*~~ *be verified under the equipment evaluation performed* **by the medical physicist** *when the equipment is initially placed in service and should be verified* ~~*periodically*~~ **as needed** *throughout* **the unit's** ~~*its*~~ *useful life.* ~~*The period of verification should be established with reference to the manufacturer's maintenance specifications and the use considerations (wear and tear) unique to the facility.*~~ *Anytime the facility or its personnel become aware of suspected problems with the equipment through its use or normal visual checks, or perhaps through observation of clinical images, the conformance of the equipment should be checked and repair or replacement should be achieved* ~~*within the times specified under 900.12(e)(8)(ii) but always within 30 days of verification of the problem*~~*. Manufacturers may specify procedures and frequency for testing the compression paddles in their maintenance instructions and adherence to these recommendations should normally be adequate; however the responsibility for compliance still remains with the facility.*

One acceptable method for performing the compression paddle deflection test is:

1. *If the mammographic unit does not have a read out of compression force, cover the bucky with a towel and place a bathroom scale on the towel.*
2. *In order to prevent measuring deflection of the image receptor support (bucky) or the scale, place a support plate on top of the scale or directly on the towel if a scale is not used. The support plate should* **be** *made of a rigid material (***e.g., an** *acrylic sheet) that is large enough to completely cover either the scale or bucky.*
3. *Place the test object on the support plate with its base along the chest wall edge of the compression plate. Examples of test objects include: compressible foam materials (e.g. T-200 Minicel foam (10 X 14 cm for the 18 X 24 cm paddle and 14 X 22 cm for the 24 X 30 cm paddle, thickness of 4 to 6 cm) or tennis or rubber balls taped together in the shaped of an equilateral triangle (3 balls for the 18 X 24 cm paddle and 6 balls for the 24 X 30 cm paddle)*
4. *Apply a compression force of 111 newtons (25 pounds).*
5. *Measure the distance of each corner of the paddle from the support plate.*
6. *Subtract the smallest distance from the largest distance to determine the deflection. The difference must be 1.0 cm or less to pass the test.*

Page 25, 21 CFR 900.12(b)

The ACR recommends the following minor modifications to the response to encourage consistent image quality:

Question: *Our mammography exams are interpreted off-site. Do we need to have a viewbox, hot light, and masking materials on-site?*

Answer: *No. Facilities are required to have these items where the exams are interpreted but are not specifically required to have them where the exams are produced. However,* **since technologists can only adjust the quality of the images provided to the**

interpreting physician based on what they can observe on-site, *FDA recommends that the above items be provided to the technologists as an* **essential** *aid in performing their duties.*

Page 27, 21 CFR 900.12(c)(1)(vi)

Regarding addendums and comparison reports: ACR clearly understands the need to give or send all women a written lay-language report following the mammogram. However, we do not understand the rationale for requiring additional lay reports be sent to women after comparison with previous mammograms (with no change in final assessment) or after an addendum is added (such as merely stating that the referring physician has been notified by phone). This greatly increases the cost of notification, since all of these lay reports must be mailed and will require the time of the radiologist to notify the breast center personnel of the need to send out these reports, as well as the time for the personnel to send out the reports. Such effort would certainly be justified if there was a change in the report (in other words, if management of the patient would change). However, given the relatively low reimbursement and the high volume of paperwork for mammography, it is hard to imagine how requirement of these additional letters can be justified. Such a requirement will be a disincentive to obtain outside mammograms for comparison and the primary reporting of mammograms (and sending of lay letters) may be delayed until the referring physician is notified by phone so that one can reduce the number of lay letters that are sent. This is not in the best interest of patient care.

Page 29, 21 CFR 900.12(c)(4)(ii)

Question: *A facility ceases operations and closes its doors. What actions should it take to avoid future MQSA problems and how should it deal with retention of mammographic medical records?*

Answer: *When a facility ceases operations and closes its doors, it should do the following:*

1. *Inform its accreditation body that it will no longer be performing mammography;*
2. *Return its facility certificate to its certifying body. For facilities where FDA is the certifying body, the certificate should be mailed to P.O. Box 6057 Columbia, MD 21045-6057;*
3. *Attempt to make arrangements to transfer each patient's medical record (original mammography films and reports) to the mammography facility where the patient will be receiving future care, the patient's referring physician, or the patient herself. This transfer will address the requirement that the facility maintain the patient's permanent medical record for a period of not less than 5 years, or not less that 10 years if no additional mammograms are performed at the facility, or longer if mandated by State or local law. Facilities should check with State or local agencies to determine if their requirements are more stringent.*

If the option in number 3 is not viable, facilities could store the medical records in a hospital, if appropriate, or make arrangements to warehouse the records. ***It should be noted that if no one else is willing to accept the records, the facility remains responsible for them.*** *Under MQSA, facilities will not be held responsible for maintenance of*

examinations performed prior to October 1, 1994; however, State and local regulations may require otherwise.

The FDA statement that "if no one else is willing to accept the records, the facility remains responsible for them" may be a difficult requirement to enforce for common cases of facility closure such as if the facility goes out of business or the owner dies.

Page 30, 21 CFR 900.12(c)(4)(iii)
The ACR recommends that facilities who's internal policies require that they copy films before transferring the originals (even though it is not required by their state or requested by the patient) should be allowed to include this with their other appropriate charges for the transfer of records. This, along with direct reporting, will bring more cost pressure to bear on mammography facilities if they are not allowed to recover their legitimate costs. We recommend the response to be modified as follows:
Question: *What are appropriate charges for the transfer of mammographic records? Can I include the cost of making copies of the films?*
Answer: *Appropriate charges for transfer of mammographic records could include items such as administrative time costs incurred in logging-in the request, retrieving the mammography films and reports, having the patient sign a release, packaging and mailing charges for the materials, and photocopying costs incurred in making copies of reports. Facilities may, but are not required by MQSA to, make copies of the mammographic films* **and** ~~*If these copies are requested by the patient or are mandated by State regulations, then*~~ *the cost of making the copies can be charged to the patient.* ~~*If the facility wishes to keep copies for its own benefit, the cost cannot be charged to the patient.*~~
Facilities must be able to produce, if requested by the patient, documentation (e.g., itemized bill) that the charges do not exceed the costs associated with this service.

Page 32, Quality Assurance, General 21 CFR 900.12 (d)(1)(iv)
ACR receives frequent questions about who is allowed to perform QC in mammography. We suggest elaborating on the answer to this question to further describe the flexibility of the regulations.
Question: *Does the quality control technologist have to be a qualified mammography technologist?*
Answer: *Yes. The regulations require that the quality control technologist meet the qualifications for performing mammography examinations.* **However, the regulations state that other qualified personnel may be used to perform certain quality control tasks but the quality control technologist designated for mammography must ensure that the tests are done to meet MQSA requirements. For example, a radiology department QC technologist may also perform and evaluate the processor QC in mammography. It is the responsibility of the mammography QC technologist to periodically review this data and documentation to make sure they meet MQSA regulations.**

Page 33, Quality Control Tests - General
The ACR recommends the following minor changes for clarification:

Question: *How often must the densitometer and sensitometer be calibrated? What should the facility do while they are out being serviced or while they are broken?*
Answer: *There are no regulatory requirements for calibrations of these devices. FDA encourages the facility to follow the manufacturer recommended calibration procedures for such devices.*
If these devices are used daily for processor performance testing, the facility should make sure they have a back up or "loaner" densitometer and sensitometer available before sending them out for servicing. Facilities should consult their equipment provider for a "loaner." In the case of broken devices, the facility may choose to **continue to perform mammography and** *batch process the films once a replacement device is obtained, provided that the time delay is short.*

Page 34, Quality Control Tests - General
The ACR agrees that all screen-film combinations should be tested as described if they are used for the average breast. However, we disagree with the guidance provided in this response if the screen-film combination is only used for special cases that are not used to image the average breast since the test conditions would not be clinically relevant. For example, it would be irrelevant to look at image quality and measure dose using the 4.2 cm "ACR" phantom for a fast screen-film combination that is only used by the facility to image breasts in excess of 8 cm. The measured dose does not predict in any way the patient dose; the attenuation and scatter conditions of the 4.2 cm phantom does not simulate those of an 8 cm breast. Furthermore, no standards are available to evaluate performance under these conditions. ACR therefore recommends modifying the response as follows:

Question: *A facility is using more than one type of screen-film combination. Must it perform the QC tests separately for each combination used?*
Answer: *It depends. For the majority of the QC tests, the type of screen-film combination used in the test is irrelevant to the test outcome. However, for the following two QC tests, the regulations spell out specific requirements:*

1. *System Resolution - must be measured for each screen-film combination used at the facility.*
2. *Phantom Image and Dose - each of these must be conducted for each screen-film combination clinically used for the average breast.*

It should also be noted that the phantom image test applies to both the weekly QC and the annual test conducted by the medical physicist as part of the survey report. **The medical physicist may choose to evaluate dose and image quality of the special-case screen-film combinations using clinically relevant phantoms and techniques during the annual survey.** ~~*If only one combination is used for the average breast and the other combination is used for special clinical studies, FDA recommends that the dose and phantom image QC tests be conducted for the other combination because the outcome of both tests is heavily influenced by the film-screen combination used.*~~

Note that testing for the uniformity of screen speed and system artifacts must be conducted for all screens and cassettes respectively. Hence by default, both include all types of screens used but this does not preclude performing either of these tests with only one type of film.

Page 35, Daily Quality Control Tests, CFR 900.12(e)(1)
This recommendation for additional days is not always practical. For example, mammography clinics may not be open 5 days a week and qualified personnel may not be available to run sensitometric strips on the days they are closed. We recommend the following slight modification:

Question: *Must a facility perform the daily processor QC tests on days when mammograms are performed but not processed?*
Answer: *No. Facilities are required to perform these tests only on the days they process mammograms; however, FDA* **suggests, if possible,** ~~*recommends*~~ *that facilities that routinely process mammograms less than 5 days/week perform the daily processor QC tests on additional days. The additional tests can provide the facility more information to predict trends and thereby identify and correct problems earlier.*

Page 35, Weekly Quality Control Tests, CFR 900.12(e)(2)
ACR recommends that the response be modified as follows to allow for improvements in image quality to be implemented:

Question: *Under what circumstances should I reestablish a new baseline optical density (OD) operating level?*
Answer: *A new baseline OD operating level may need to be established when switching to a new type of film,* ~~*or*~~ *if the* **automatic exposure control** *density selector settings in the mammographic unit have been re-calibrated during servicing of the unit* **or if the interpreting physician(s) have made an intentional decision to modify background optical densities of clinical images. For example, many facilities are choosing to increase film densities to take advantage of the film's increased contrast and the higher luminance levels available in today's viewboxes.**

Page 42, Calibration of air kerma measuring instruments 21 CFR 900.12(e)(12)
For clarity, we suggest the following minor modification:

Question: *How should the physicist indicate to the mammography facility that the air kerma measuring instrument has met the requirement?*
Answer: *The physicist should include the date of the last* ~~*requirement fulfilling*~~ *calibration in the annual physics survey report. The physicist must retain, in his or her records, the documentation (letter, certificate, report, etc.) from the calibration laboratory showing:*

1. *the date of the instrument's calibration.*
2. that the instrument met the required accuracy or if it did not, the correction factors that must be used to bring the measurements within the required accuracy.

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